HOW HEALTH CARE REFORM AFFECTS PHARMACEUTICAL RESEARCH AND DEVELOPMENT

The Congress of the United States
Congressional Budget Office

NOTES

Numbers in the text and tables may not add up to totals because of rounding.

Preface

The Congressional Budget Office (CBO) has prepared this report as part of its continuing analysis of the Administration's and other health care reform proposals. The report contains a general view of the provisions in the Administration's proposal that concern pharmaceutical benefits and costs. It also examines the effect of those provisions on the demand for drugs and on the incentives they offer pharmaceutical companies to invest in research and development. In keeping with CBO's mandate to provide nonpartisan analysis, the report includes no recommendations.

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Summary

In the fall of 1993, the Administration introduced a comprehensive proposal for health care reform. The Administration's proposal attempted to balance the desire for increased access to medical care with the need to control costs, both overall and in the specific case of pharmaceuticals. This report concentrates on how proposed changes in health care policy--primarily universal coverage and improved Medicare benefits--are likely to affect the size and composition of the pharmaceutical market and the incentives of drug companies to engage in research and development (R&D). The provisions in the Administration's proposal for health care reform that deal explicitly with pharmaceuticals focus mainly on outpatient prescription drugs. In general, the insurance status of inpatient and over-the-counter pharmaceuticals would not be changed directly, though the economic incentives facing those who produce and consume them are likely to change.

Although the study focuses on the Health Security Act, many of that plan's features are also included in other proposals for health care reform. Wherever those other proposals contain provisions similar to the ones examined here, the same analysis would apply.

Industry R&D and Market Structure

Pharmaceutical expenditures have been rising both in real terms and as a share of national health expenditures. The share of prescription drug spending, excluding most over-the-counter drugs, accounted for 6.4 percent of total national health expenditures in 1991, up from 4.4 percent in 1981. As a share of gross domestic product (GDP), prescription drug spending rose during most of this period, reaching 0.8 percent of GDP in 1991. Outpatient prescription drugs account for three-quarters of all pharmaceutical sales. Other pharmaceuticals are administered in inpatient settings, such as hospitals. In 1993, U.S. prescription sales exceeded $55 billion, according to industry figures.

Industry R&D

Research and development in the pharmaceutical industry (both foreign and domestic) has increased continuously for the last two decades, both in absolute terms and as a percentage of sales. According to industry figures, in 1993 domestic R&D funded by the industry reached $10.3 billion, or 18 percent of sales. The high level of R&D in this industry, together with relatively low production costs, has created a cost structure that encourages companies to seek ever-larger markets for their products, even if this requires substantial price discounts. The reason is that once a product is developed and approved for sale, it has already incurred R&D costs. Additional sales, even at deep discounts, serve to spread the R&D costs. The fact that pharmaceutical companies can offer some consumers price reductions that they do not offer to others also encourages discounting.

The high technical levels fostered by R&D, coupled with a favorable cost structure, have resulted in

a domestic industry that is very competitive internationally. U.S. firms developed almost half of the important new drugs--those that are sold in all major markets around the world--that were introduced between 1970 and 1992. According to the Department of Commerce, U.S. firms sold one-half (by value) of the world's pharmaceuticals that were consumed in 1991.

The Changing U.S. Market

Seventy percent of prescriptions are for drugs that are manufactured by more than one company. Even the remaining 30 percent, however, often face competition by substitutes.

On a scale ranging between a perfect monopoly and perfect competition, the pharmaceutical industry can probably best be described as imperfectly competitive; firms have some power to raise prices and generate excess profits. Observers suggest, however, that recent events in the pharmaceutical market are undercutting this power somewhat and serving to move the industry in the direction of more competition.

The market is changing. On the supply side, sales of generic drugs are increasing. On the demand side, buyers exercise more market power to reduce the profits of the pharmaceutical companies. Demand-side changes include the spread of companies devoted to managing the pharmaceutical benefits for third-party payers, such as health insurance companies, and the expansion of the market share of managed health care providers. Both of these groups use a variety of techniques to reduce pharmaceutical costs, including aggressive negotiations with pharmaceutical companies, restrictive drug utilization lists, and widespread use of generic drugs. Although the use of these techniques is growing, only a small fraction of buyers currently employ them, and even then inconsistently. Still, as a share of total prescription sales, the volume of generic drugs has increased from 23 percent in 1980 to almost 40 percent. Furthermore, patents on many of the top-selling drugs will expire in the next few years, opening the door to even more competition among manufacturers of generic drugs.

Provisions That Increase Demand for Prescription Drugs

The Congressional Budget Office (CBO) has analyzed two provisions of the Administration's proposal that are likely to increase demand for prescription drugs directly: a universal entitlement to a comprehensive package of health benefits, including reimbursement for prescription drugs (universal coverage), and the addition of a prescription drug benefit to Medicare, which is the primary source of health insurance coverage for the population that is 65 years old and older.

CBO's estimate of the change in demand for pharmaceuticals omits several provisions of the Administration's proposal, usually because these provisions proved impossible to quantify, even approximately. For example, CBO provides no estimate of the way in which shifts to managed care providers would affect the use of prescription drugs, although anecdotal evidence suggests that managed care providers use more prescription drugs than do fee-for-service providers. In addition, incentives facing providers would change under the Administration's proposal and might affect the use of drugs.

The proposed provision of universal coverage, including a drug benefit, would increase total prescription drug expenditures by 3 percent to 5 percent. Adding a drug benefit to Medicare would increase total prescription drug expenditures by 1 percent. CBO estimates that these provisions of the Administration's proposal would increase total expenditures on all prescription drugs by 4 percent to 6 percent.

Effects of the Administration's Proposal for Universal Coverage on Drug Demand

The Administration's proposal would extend health insurance coverage to all legal residents of the United States. The under-65 population would be

covered by one of three basic types of plans, each of which would include coverage for hospitalization, physician visits, and outpatient prescription drugs. The drug benefit in the Administration's proposal for the high-cost-sharing option would pay 80 percent of the cost of prescription drugs after a $250 deductible had been met. If a person were to enroll in the low-cost-sharing option, he or she would pay $5 per prescription with no deductible. The combination plan would offer the low-cost-sharing benefits when a patient used a plan's network of health care providers. Otherwise, the high-cost-sharing benefits would apply. All three plans would place an annual limit of $1,500 per individual ($3,000 for families) on all out-of-pocket medical expenses.

Universal coverage under the Administration's proposal would have the greatest impact on demand for prescription drugs by extending benefits to the 37 million people under age 65 who are currently uninsured. Under the comprehensive benefits proposed, coverage would also improve for another 8 percent of the under-65 population who are insured. But most of the population under 65 already has hospital, physician, and drug coverage through an employer, similar to that included in the Administration's proposal. CBO estimates that universal coverage, including the proposed drug benefit, would increase demand by the under-65 population for all prescription drugs by 5 percent to 7 percent. It is primarily the demand for outpatient prescription drugs that would rise. The under-65 population currently accounts for two-thirds of all prescription drug sales. Thus, universal coverage would increase the total demand of the entire population for all prescription drugs by 3 percent to 5 percent.

Effects of the Administration's Proposal for Expanded Medicare Benefits on Drug Demand

Under Medicare, everyone 65 and over and eligible for Social Security is automatically entitled to hospitalization benefits. So are certain disabled people under 65 and some people with severe renal disease. All people who are 65 and over, as well as other people who are eligible for Medicare's hospitalization benefits, may participate in Medicare's Supplementary Medical Insurance program, which covers physician, outpatient hospital, and independent laboratory services. Participants must pay a monthly premium. Supplementary Medical Insurance, to which the drug benefits would be added, covers 95 percent of the 65-and-over population.

Under the Administration's proposal, Medicare beneficiaries would for the first time have a prescription drug benefit as part of their basic coverage. That benefit would be approximately commensurate with the high-cost-sharing option available for the rest of the population under the Administration's proposal. The benefit would pay 80 percent of the cost of prescription drugs after a $250 deductible had been met. Once the recipient had paid $1,000 in out-of-pocket prescription drug expenses, Medicare would cover all pharmaceutical purchases for the year. The Medicare Supplementary Medical Insurance premium would be increased to pay for one-quarter of the cost of the new drug benefits. The new Medicare coverage would also encourage substitution of generic drugs unless otherwise requested by the physician.

By itself, adding the prescription benefit would not be likely to increase pharmaceutical purchases by the 65-and-over population dramatically. Just over half of the 65-and-over population already has supplemental coverage for prescription drugs, primarily through retirement plans. In addition to the basic benefits they get from Medicare, most 65-and-over Medicare beneficiaries also have supplemental coverage for physician services. Many analysts believe that access to physicians is a major factor determining prescription drug expenditures, perhaps more important than drug coverage itself. Consequently, CBO estimates that outpatient drug expenditures for the entire 65-and-over population would rise by only 4 percent if prescription drug coverage were extended to it as a basic benefit. Currently, this population accounts for one-third of all prescription drug purchases. The estimated increase in expenditures for outpatient drugs by Medicare beneficiaries corresponds to a 1 percent rise in the total prescription drug expenditures of the entire population.

Provisions That Control Costs

The Administration's proposal attempts to control health costs, both directly and indirectly. Most important, it would control the rate of increase in the premiums that health plans could charge for the standard benefit package and would result in major changes in the structure of the health care marketplace. For prescription drugs, rebates and close inspection of introductory prices of new drugs may be the most important direct mechanisms. In addition, indirect effects on the medical care delivery system, such as through increased enrollment in health maintenance organizations that may substitute drugs for surgical or other medical procedures, could be substantial, but they cannot be measured without appreciable error and are not analyzed quantitatively in this study.

Medicare Rebates

In order to reduce the impact of the expanded Medicare benefit on the taxpayer, the Administration's proposal includes a rebate of at least 17 percent that pharmaceutical manufacturers would have to agree to pay to the government on all brand-name (nongeneric) prescription drugs purchased on an outpatient basis by Medicare beneficiaries. (The rebate on drugs purchased by Medicaid enrollees would end.) The Medicare rebate would be based on the "average manufacturer retail price," which is defined as the price paid to pharmaceutical manufacturers for drugs that are sold through pharmacies and other retailers.

The rebate would increase if the difference between the average manufacturer retail price and the average price paid by institutional purchasers, such as hospitals, exceeded 17 percent. In that case, the rebate would equal the average discount given to institutional purchasers. If the amount of the drugs consumed by Medicare beneficiaries was sufficiently large in relation to the total demand for the drug, the manufacturer would be likely to keep the average discount rate afforded institutional purchasers at or below 17 percent.

This rebate would assure that the government paid no more on average for a drug purchased through Medicare than institutional purchasers do, and would sometimes pay less. The rebate would probably have a much greater effect on drug company profits than the price discount given to a typical institution. People who are 65 years old or older account for one-third of prescription drug sales, but each institution represents only a small fraction of the total market.

The rebate would also increase if the average manufacturer retail price of a drug rose faster than the rate of inflation as measured by the consumer price index. In addition, manufacturers would not be able to exclude a portion of their drugs that are already on the market from the rebate agreement. Either all of the manufacturer's existing drugs or none would be covered by Medicare.

Based on a sample of 100 patented drugs on which the Medicaid program currently spends the most money, CBO found that the median best discount given to institutional purchasers was 18 percent off the average manufacturer price (approximately the price paid by wholesalers and the Medicaid rebate equivalent of the "average manufacturer retail price"). Since the *average* discount given to institutional purchasers would be lower than the *best* discount given to any institutional purchaser, the average amount that brand-name drugs are discounted for institutional purchasers may often be below 17 percent.

Discounts are currently smaller than they might be in the absence of Medicaid rebates. The incentive to give institutional buyers discounts in excess of 17 percent on drugs purchased by people 65 and over would diminish, but perhaps no more so than it has already under the Medicaid rebate agreement.

Medicare Rebates on New Drugs

For any prescription drug that was first marketed after June 1993, Medicare could negotiate a special rebate if the Secretary of Health and Human Services (HHS) believed the drug was priced excessively or if the drug was marketed abroad at a lower

price. The drug company and the Secretary would have six months from the date of the approval by the Food and Drug Administration (FDA) to negotiate a rebate agreement. If HHS and the company failed to negotiate such an agreement, the Secretary could refuse to reimburse purchases of the drug under the Medicare drug benefit. Without this provision, drug companies would be more likely to try offsetting the rebate by charging higher launch prices.

A special rebate could be negotiated if the price in one or more of almost two dozen foreign--mostly European--countries was significantly below the introductory price in the United States. Since it is unlikely that U.S. introductory prices of any given drug would be lower than the prices in all of these countries, all new drugs could be subject to special rebate negotiations.

Although much of the policy debate has been focused on breakthrough drugs, imitative ("me too") drugs also play a major role in the pharmaceutical market. By providing a therapeutic alternative, these drugs can make a market more competitive well before the patent on the original drug expires, thus limiting the ability of a breakthrough drug's manufacturer to sustain excessive prices. Under the Administration's proposal, only generic drugs would be exempt from the rebate on new drugs. If the Medicare rebate on new drugs is set too high, it could discourage competition and early entry. Given the uncertainty inherent in deciding on a reasonable price, the rebate provision increases the risk of launching new drugs. Similarly, if the rebate is extended to generic drugs, it might also discourage entry. These effects would not be felt immediately because drug companies would probably finish those projects that are nearing completion.

The actions of Medicare, sometimes in conjunction with the Advisory Council on Breakthrough Drugs, could give the federal government a major influence over the prices of many pharmaceuticals. Under the Administration's proposal, the Secretary of HHS would negotiate the initial rebate, based on the "reasonableness" of the launch price. After the launch period, the Medicare rebate would increase if a pharmaceutical company raised its prices above the rate of inflation. Consequently, the federal government would be sending strong signals to manufacturers on launch price and subsequent price increases. The combination of these policies would not have as much force as formal price controls, but would go against a longstanding trend of eliminating price and quantity controls and keeping health and quality regulations.

Advisory Council on Breakthrough Drugs

Under the Administration's proposal, when any new drug that represents a significant therapeutic advance is approved by the FDA, the launch price would be subject to review by a 13-member Advisory Council on Breakthrough Drugs. This council, appointed by the Secretary of HHS, would be responsible for determining whether a launch price was "reasonable" or not, basing its judgment on related and foreign drug prices; manufacturer's costs, including R&D; various market forecasts; the cost effectiveness of the drug; and its potential contribution to the quality of life. The Secretary of HHS would publish the council's determination, together with minority opinions, in the *Federal Register*. Presumably, the Advisory Council's judgment would be a significant factor in the Medicare rebate negotiations and might affect private negotiations as well. Because the council would deal with all breakthrough drugs, its responsibilities would extend beyond Medicare.

Depending on how the proposed legislation is interpreted, however, the Advisory Council could play a role in just a very small number of drug introductions. Between 1975 and 1991, the FDA approved an average of 22 new drugs (containing new active ingredients, or "new molecular entities" in FDA parlance) per year. The breakthrough category, promising major new therapeutic potential, accounted for one-seventh of all new molecular entities, or about three drugs each year. Including drugs with only modest therapeutic improvement would increase this number to 11 per year.

Although only a few drugs can be classified as breakthroughs, many companies undertake their R&D with the intent of developing just such pharmaceuticals. Thus, even though the number of

drugs directly involved might be small, the inhibiting effect on pharmaceutical companies could be much greater.

Effects on the Returns from Drug Development

Underlying the Administration's proposal are two conflicting effects: the extension of drug benefits to the entire population could increase the total demand for prescription drugs by 4 percent to 6 percent, boosting profits of pharmaceutical manufacturers; but rebates on drugs sold to Medicare patients and other cost controls could limit profits (or returns). The net effect on returns from drug development would be small and positive when averaged among all drugs, but would differ among drugs and could be negative for some.

Estimated profits from drug development, averaged among all drugs and outpatient markets, would

Summary Table 1.
The Effect of the Administration's Proposal on the Present Value of Profits Generated Over the Lifetime of the Average Drug

Administration's Proposal	Description	Effect on the Presciption Drug Market	Change in Average Profits from Developing a Drug (In percent)[a]		
			Drugs Purchased Only by People Under 65	Drugs Purchased Only by People 65 and Over	Drugs Purchased Two-Thirds by People Under 65, One-Third by People 65 and Over (Market average)[b]
Universal Coverage	The proposal contains a universal entitlement to a standard benefit package that includes prescription drug coverage. Primarily affects the under-65 population.	Expenditures by the under-65 population on all pharmaceuticals would rise by 6 percent.	8	0	6
Medicaid Becomes Part of the Alliance System	Government would fully subsidize participation of most Medicaid recipients in the alliance system.	Medicaid rebates would be eliminated. Average unit revenues on outpatient sales would rise by 2 percent.	3	3	3
Drug Benefit Added to Medicare	Medicare would cover outpatient drugs. A rebate of at least 17 percent would be imposed on outpatient drugs purchased through Medicare.	Expenditures by the 65-and-over population on outpatient pharmaceuticals would rise by 4.5 percent. Unit revenues would decline by 17 percent.	0	-17	-6
		Total	11	-14	3

SOURCE: Congressional Budget Office.

a. Change in the discounted value of the stream of profits generated by the worldwide sales of the average drug over its lifetime.

b. On average, people 65 and over account for 34 percent of prescription drug expenditures.

rise modestly--by less than 3 percent--under the Administration's proposal. Consequently, the level of industry R&D might not change appreciably, given the small changes in total returns from drug development. (See Summary Table 1.)

Behind this average, however, market segments would vary significantly. Profits would fall by an average of 14 percent on those drugs that are sold exclusively to the 65-and-over population and would rise by 11 percent on those drugs sold exclusively to the under-65 population. Although few drugs are marketed exclusively to either population, CBO's analysis found that under the Administration's proposal, once half of the market for a drug was made up of sales to the 65-and-over population, returns would decline slightly.

A decline in the profits from developing pharmaceuticals primarily for the 65-and-over market would reduce the incentives to produce such drugs. The difference in returns on the basis of age groups might cause some R&D to be shifted away from drugs targeted at those 65 and over toward drugs aimed primarily at those under 65.

These estimates should not be viewed as CBO's final analysis of the overall effects of the Administration's proposal. Rather, they are best viewed as illustrative estimates of the portion of the proposal that CBO was able to quantify. Although the factors omitted could serve to increase or decrease returns, CBO's sensitivity analysis showed that large variations in the assumptions about induced demand do not change the overall result--namely, that the proposal would affect average profits from drug development only slightly.

CBO's calculations assume that the manufacturers entirely absorb the cost of the 17 percent Medicare rebate. Such burdens, however, are usually shared between producers and consumers according to their relative sensitivity to changes in price. But because the Administration proposes to monitor launch prices and price increases, pharmaceutical companies might find it difficult to pass these rebates on to other consumers. Consequently, the drug companies would probably absorb a very large share of the rebate.

However, the more Medicare administrators are able to make pharmaceutical producers absorb the cost of the rebate, the less incentive these producers will have to invest in developing new drugs for the 65-and-over market. By contrast, the less Medicare administrators are able to make the pharmaceutical companies absorb the rebate, the more other drug consumers will pay for the Medicare benefits.

CBO's estimates assume that the federal government could enforce price restraints. But that is an open question. Many times in the past the federal government has tried to restrain price growth, usually with mixed results at best. The modern market is too complicated for a limited bureaucracy to track and control successfully. Prices in the drug market are especially complicated; drug prices vary in many dimensions (dosage, form, and packaging, to name only three), any one of which could be used to mask a price increase. Given the hundreds of drugs and manufacturers and the thousands of dosage and packaging forms, the federal agencies in charge of monitoring drug prices would have to rely on the basic compliance of the drug companies, as they do now for the Medicaid rebate. Such reliance often leads to incomplete compliance.